Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy and safety of SAMANIK RELAX® (magnesium citrate) in the treatment of functional constipation: a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim
To evaluate the efficacy and safety of SAMANIK RELAX® (magnesium citrate) in treating functional constipation
Design
Randomized, double-blind, placebo-controlled clinical trial with block randomization
Settings and conduct
Conducted at Baqiyatallah Hospital/University. Participants are randomized, undergo 4 weeks of intervention with weekly monitoring. Data collected via diaries and Bristol Stool Form Scale.
Participants/Inclusion and exclusion criteria
Inclusion: Ages 18–60, functional constipation diagnosed via Rome IV criteria. Exclusion: Pregnancy, organic gastrointestinal/renal diseases, concomitant laxative use
Intervention groups
Intervention group (SAMANIK RELAX®, two sachets daily) and Control group (placebo, two sachets daily)
Main outcome variables
1) Frequency of spontaneous bowel movements per week, 2) Mean Bristol Stool Scale score (stool consistency), 3) Incidence of adverse events (safety)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210325050769N3**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**
Registration date
2026-05-05, 1405/02/15

Registrant information
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-05-10, 1405/02/20
Expected recruitment end date
2026-11-21, 1405/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and safety of SAMANIK RELAX® (magnesium citrate) in the treatment of functional constipation: a randomized, double-blind, placebo-controlled clinical trial

Public title
Magnesium citrate in functional constipation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with functional constipation based on Rome IV criteria Aged 18-60 years Filling consent form
Exclusion criteria:

Pregnancy Lactation Organic gastrointestinal diseases (IBD, obstruction, tumors) History of gastric/bowel surgery Advanced renal/hepatic/cardiac diseases Concurrent use of laxatives or drugs affecting gut motility

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

The study utilizes block randomization with blocks of four. The random sequence is generated using Microsoft Excel 2019 software via a custom module defined in the Visual Basic for Applications (VBA) environment. In this method, treatment blocks for the two groups (intervention and control) are randomly permuted (e.g., possible permutations for a block of 4 include AABB, ABAB, etc., with equal probability). The final randomization list is prepared by a person independent of the research team and placed in sealed envelopes. After recording patient details, the researcher randomly selects one envelope to assign the patient to either the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is designed as a double-blind trial. 1. Physical Appearance: The placebo is prepared as a powder with a color and taste (blueberry) similar to the active product, but without the active ingredient (Magnesium Citrate). The packaging, labeling, sachet color, and distribution boxes (two 28-sachet boxes) are identical for both groups, making it impossible to distinguish between the intervention and placebo visually. 2. Blinding of Patients and Physicians: Both the patients and the treating physician/researcher are unaware of the assigned intervention (SAMANIK RELAX® or placebo). Each patient is assigned a unique identification code by the physician, who remains blinded to the group allocation. 3. Blinding of Assessors: To assess stool consistency using the Bristol Stool Form Scale, patients send photos of their stool. These images are evaluated by a trained member of the research team who is strictly blinded to the patient's group assignment. 4. Blinding of Analysts: At the end of the study, only one team member, who was not involved in data collection or assessment, holds the key linking codes to group assignments. Prior to statistical analysis, this individual reclassifies the codes into Group A (Placebo) and Group B (SAMANIK RELAX®) and provides the coded dataset to the statistical analyst. Thus, the data analyst is also blinded to the group allocation.

Placebo

Used

Assignment

Parallel

Other design features

Randomized, placebo-controlled, parallel-group, double-blind clinical trial. Intervention duration is 28 days (one month). Follow-up includes daily phone calls for data recording in diaries and clinic visits at week 2 and week 4. Efficacy assessment is based on Rome IV criteria and Bristol Stool Form Scale.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Mulla Sadra, Vanak Square, Tehran, Iran

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Approval date

2026-03-17, 1404/12/26

Ethics committee reference number

IR.BMSU.REC.1405.015

Health conditions studied

1

Description of health condition studied

Functional constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Frequency of Spontaneous Bowel Movements (SBMs) per Week

Timepoint

Data is collected daily in the patient’s diary, and the weekly mean is calculated at the end of Week 2 and

Week 4 (end of intervention)

Method of measurement

Self-reported by participants in a daily diary and verified by researchers during follow-up visits (Weeks 2 and 4)

2

Description

Stool Consistency (Mean Bristol Stool Scale Score)

Timepoint

Recorded daily in the diary; the weekly mean is calculated at the end of Week 2 and Week 4

Method of measurement

Participants record the score in their diary and submit one photo of their stool per week. The score is validated by a trained, blinded investigator who assesses the photos and diary entries independently of the treatment group.

Secondary outcomes

1

Description

Time to Onset of Therapeutic Effect

Timepoint

Recorded daily in the diary; analyzed at the end of week 2 and week 4

Method of measurement

Calculated by identifying the date of the first successful spontaneous bowel movement or stool consistency improvement in the patient's daily logs.

2

Description

Adverse Events (Safety)

Timepoint

Daily monitoring via reminder phone calls and diary entries; final assessment at in-person visits at the end of week 2 and week 4

Method of measurement

Type, severity, and duration of each adverse event are recorded. Severity is classified according to standard criteria (mild, moderate, severe).

Intervention groups

1

Description

The intervention group receives two sachets of SAMANIK RELAX® (containing magnesium citrate) daily, with each sachet providing 300 mg of elemental magnesium. Participants are instructed to dissolve each sachet in 200 ml of water and consume it separately in two divided doses (morning and evening). The use of other laxatives is prohibited during the study, except in cases of no bowel movement for more than 72 hours, where glycerin enema is permitted as a rescue medication and recorded.

Category

Treatment - Drugs

2

Description

The control group receives two placebo sachets daily, which are identical in appearance, color, packaging, and taste (blueberry) to the active product but contain no active ingredient (magnesium citrate). Participants in this group are instructed to consume the placebo exactly as the intervention group, dissolving each sachet in 200 ml of water in two divided doses (morning and evening). The monitoring protocol for adverse effects and restrictions on laxative use are identical to those in the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Mohammad Ali Abyazi Heris

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Samanik Salamat Gostar Pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Ali Abyazi Heris

Position

Assistant Professor of Gastroenterology and Hepatology

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology and Hepatology

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after un-identification of individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic centers as well as to industry professionals.

Under which criteria data/document could be used

Statistical analyzes on data are allowed for scientific and research use after obtaining permission from the project manager.

From where data/document is obtainable

For data and documentation, refer to the Research Center for Gastroenterology and Liver Diseases and Dr. Mohammad Heiat.

What processes are involved for a request to access data/document

After receiving a written request from researchers... by the Baqiyatallah Research Center for Gastroenterology and Liver Disease and reviewing the application in the Research Council of the Research Center, the documents or data files will be delivered to the applicant after about 10 days.

Comments